

ON-SITE ASSESSMENT
APPENDIX D

**CRITICAL PERFORMANCE ELEMENTS OF
TEST METHODS AND ASSESSMENT
PROCEDURES**

PROPOSED CHANGES

D.1 Introduction

One function of on-site assessments is to evaluate the capability of a laboratory to perform the test methods for which it seeks or maintains accreditation. Regulatory programs employ various approaches to producing data of known and documented quality including requiring the use of promulgated methods (e.g. Safe Drinking Water Act) or specifying data acceptance criteria in regulations or permits. Chapter 5 of the NELAC Standards requires laboratories to maintain Standard Operating Procedures (SOPs) and Laboratory Methods Manuals, and defines their format.

Assessors review laboratory testing protocols to not only evaluate conformance to reference methods, but also to determine the effectiveness of a laboratory's quality system. Thus, in reviewing test methods, assessors also verify that a laboratory's quality system and practices ensure that all its analytical activities produce data of known and documented quality.

Appendix D specifies critical performance elements of test methods and the process for evaluating them during assessments. Critical performance elements of test methods are those that directly affect data quality and data defensibility.

D.2 Evaluation Phases

Appendix D requires that assessors evaluate critical performance elements of test methods by thoroughly completing each of these three phases:

1. Review of Laboratory Test Method Documented Procedures
Assessors must confirm that laboratory SOPs or Methods Manuals:
 - a. Document all tests performed by a laboratory.
 - b. Address or reference all critical performance elements of test methods.
 - c. Are modified or revised in conformance to the laboratory's quality system.
2. Verification of Proper Execution of Test Methods
Assessors must verify that analysts complete critical performance elements of test methods and determine whether analysts adhere to laboratory SOPs or Methods Manuals by:
 - a. Direct observation of analysts performing test methods.
 - b. Interviewing analysts that perform test methods.
 - c. Inspecting areas where test methods are performed.
3. Audit of Data Generated Using Test Methods
Assessors must ascertain that:
 - a. Results reported are traceable to their raw data.
 - b. Results reported can be traced back to calibration data and quality control indicators
 - c. Documents associated with reported results validate or verify the correct execution of a test method.

D.3 Critical Performance Elements

The following outline specifies critical performance test method elements. Although these elements apply to a broad range of test methods and analytical disciplines, assessors may at times encounter test methods for which some of these elements are not applicable. This possibility does not constitute an allowance for assuming the inapplicability of a critical performance test element without an informed determination of this claim by a trained assessor.

In all cases, assessors must ensure that the specifications and criteria of critical performance elements are acceptable and appropriate for the intended purpose of the data generated using a test method and are in conformance with the NELAC Standards.

1. Test Method Documentation
 - a. Written procedure conforming to section 5.10 of the Standards.
 - b. Description of all steps necessary to determine the presence, identity, or concentration of an analyte in a sample.
 - c. Demonstrations of capability of all analysts or work cells performing the test method conforming to section 5.10.2.1 of the Standards.
2. Laboratory Support Equipment
 - a. Availability and use of support equipment (e.g. thermometers, balances, volumetric devices).
 - b. Calibration or standardization procedures.
 - c. Maintenance procedures.
 - d. Corrective actions and contingency procedures undertaken in the event of equipment failure.
3. Reagents and Standards
 - a. Availability and use of reagents, standards, and biological media.
 - b. Purity of standards, reagents, and biological media.
 - c. Verification of identity and concentration of prepared standards.
4. Laboratory Instruments
 - a. Availability and use of analytical instruments.
 - b. Standardization, tuning, or instrument setup.
 - c. Calibration procedures including:
 - i. Calibration range.
 - ii. Number and concentration of calibration standards.
 - iii. Calibration algorithm.
 - iv. Reduction of calibration data.
 - v. Frequency of calibration checks or of recalibration.
 - d. Maintenance procedures.
 - e. Corrective actions and contingency procedures undertaken in the event of instrument failure.
5. Sample Preparation and Analysis
 - a. Use of sample preparation techniques (e.g. filtration, aliquot selection, digestion, distillation, extraction).
 - b. Use of clean-up procedures.
 - c. Treatment of interferences before or during analysis.
 - d. Arrangement of analysis sequence or run.
6. Quality Control Indicators
 - a. Type and frequency of positive and negative controls.
 - b. Sensitivity and selectivity of analyses.
 - c. Acceptance criteria.
 - d. Corrective actions and contingency procedures undertaken when quality control indicators do not meet acceptance criteria.
7. Data Reporting and Documentation
 - a. Collection, documentation, and retrieval of raw data.
 - b. Raw data media (e.g. hard copy, electronic), storage, and security.
 - c. Capacity for reconstructing final results.
 - d. Chronology of data reduction operations.
 - e. Formulas used to derive quantitative results.
 - f. Procedures for confirming or verifying qualitative assessments of reported analytes.
 - g. Traceability of data to test methods, analysts, and instruments used to derive them.
 - h. Procedures for allowing manual correction of raw data (e.g. manual integration) and for overriding instrument qualitative results.
 - i. Procedures for data review.

